



Application No. 08/716,169  
Received dated: September 20, 2005  
Attorney Docket No. 0470-961125

*DFW*

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No. : 08/716,169  
Applicants : Stephen M. Anderton et al.  
Filed : December 17, 1996  
Title : PEPTIDE FRAGMENTS OF MICROBIAL  
: STRESS PROTEINS AND PHARMACEUTICAL  
: COMPOSITION MADE THEREOF FOR THE  
: TREATMENT AND PREVENTION OF  
: INFLAMMATORY DISEASES  
Group Art Unit : 1644  
Examiner : Patrick J. Nolan, Ph.D.  
Confirmation No. : 5487  
Customer No. : 28289

Mail Stop Petition  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

PETITION TO WITHDRAW  
NOTIFICATION OF ABANDONMENT UNDER 37 C.F.R. §1.181(a)

Applicant's petition for withdrawal of the Examiner's holding of abandonment, which was issued in error on August 23, 2005. The August 23, 2005 Notice of Abandonment asserts that no response was filed to the February 10, 2005, non-Final Office Action. However, a complete response was indeed timely filed, and a copy of the response and a copy of the USPTO postcard receipt are both attached. As provided in MPEP Section 711.03(c), in the comments following the regulatory citations, it is specifically provided that this request for withdrawing the

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Dana Rumbaugh  
(Typed Name of Person Mailing Correspondence)  
*Dana Rumbaugh* 09/20/2005  
Signature Date

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Examiner's holding of abandonment is a petition which does not require a fee—as Examiner Nolan has specifically cited in his telephone call to the undersigned on September 15, 2005.

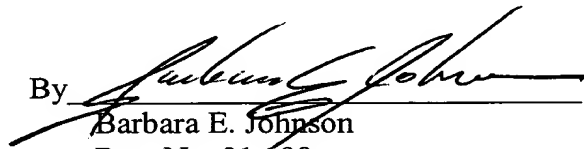
Withdrawal of the Examiner's holding of abandonment and resumption of prosecution of the above-identified patent application are respectfully requested. The undersigned asks the Examiner to telephone the undersigned at her direct dial telephone number 412-227-3020 upon receipt of the application, to discuss the reasons why this application is in condition for allowance and why such allowance should proceed without delay.

Should any fee be required notwithstanding the above, the Commissioner for Patents is hereby authorized to charge Deposit Account No. 23-0650.

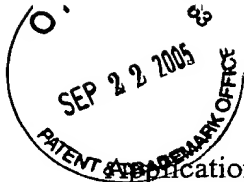
Respectfully submitted,

THE WEBB LAW FIRM

By



Barbara E. Johnson  
Reg. No. 31,198  
Attorney for Applicants  
700 Koppers Building  
436 Seventh Avenue  
Pittsburgh, PA 15219-1845  
Telephone: 412-471-8815  
Facsimile: 412-471-4094  
E-mail: [webblaw@webblaw.com](mailto:webblaw@webblaw.com)



**COPY**

Application No. 08/716,169  
Paper dated: July 8, 2005  
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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**RESPONSE**

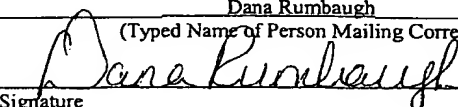
Sir:

Applicants submit the following response to the Office Action dated February 10, 2005. A Petition for Extension of Time is filed concurrently herewith.

**Amendments to the Claims** begins on page 2 of this document.

**Remarks** begin on page 4 of this document.

I hereby certify that this correspondence is being deposited with the United States Postal Service at first class mail in an envelope addressed to Board of Patent Appeals and Interferences, United States Patents and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450 on July 8, 2005.

Dana Rumbaugh  
(Typed Name of Person Mailing Correspondence)  
  
Signature Date July 8, 2005

### CLAIMS

This listing of the claims will replace all prior versions, and listings, of the claims in the application:

#### Listing of Claims

1-23 (Cancelled)

24. (Previously Presented) A method of treatment of or protection against an inflammatory disease, including autoimmune diseases, such as diabetes, arthritic diseases, atherosclerosis, multiple sclerosis, myasthenia gravis, comprising administering an effective amount of a peptide of 7-30 amino acids having the sequence of a part of the amino acid sequence of a microbial protein having a conserved mammalian stress protein homologue, said part comprising a T cell epitope corresponding to a T cell epitope of the mammalian homologue, said part further comprising at least 5 amino acids which are identical with corresponding amino acids in the same relative position in a T cell epitope of said mammalian stress protein, said epitope and said part containing at least 4 consecutive amino acids which are identical with the corresponding mammalian stress protein amino acids and thereby forming said T cell epitope corresponding to a T cell epitope of a mammalian homologue.

25. (Previously Presented) The method of claim 24, wherein said stress protein is selected from heat-shock proteins and stress-induced enzymes.

26. (Previously Presented) The method of claim 25, wherein said heat-shock protein is heat shock protein hsp65 of *Mycobacterium tuberculosis* (identical to hsp65 of *M. bovis* BCG) as depicted in SEQ ID NO. 1.

27. (Previously Presented) The method of claim 26, wherein the peptide comprises at least 5 amino acids which are identical with the corresponding amino acids in the same relative position in one of the sequences 81-100 and 241-270 of SEQ ID NO. 1.

28. (Previously Presented) The method of claim 27, wherein the peptide comprises at least 5 amino acids which are identical with the corresponding amino acids in the same relative position in one of the sequences 84-95 and 256-265 of SEQ ID NO. 1.

29. (Previously Presented) The method of claim 24, wherein one or more of the amino acids residues has been exchanged with a residue of an amino acid having similar size, charge and polarity, or with amino acid mimetics resulting in one or more backbone modifications.

30. (Previously Presented) The method of claim 24, wherein said part does not contain one or more sections of 5-30 amino acids corresponding to T cell epitopes of said microbial protein, the T cell which epitope of said microbial protein having less than 4 consecutive amino acids which are identical with the corresponding amino acids of said mammalian stress protein amino acids, such that said peptide includes a microbial T cell epitope having sufficient sequence identity with a T cell epitope of said mammalian stress protein homologue and lacks any microbial T cell epitope which does not have sufficient sequence identity with corresponding amino acids of said mammalian stress protein homologue.

31. (Previously Presented) The method of claim 24, wherein the peptide is administered parenterally, orally or nasally.

32. (Previously Presented) The method of claim 31, wherein the peptide is administered nasally.

**REMARKS**

Claims 24-31 stand rejected under 35 U.S.C. 102(b) for asserted anticipation by U.S. Patent No. 5,268,170 to VAN EDEN ("the reference"). The assertion is that the claim, by virtue of the word "comprises," is open to peptides of 4-70 amino acids in length. In this instance, however, it is not the word "comprises" which governs, but the recitation, "administering an effective amount of a peptide of 7-30 amino acids." The "7-30 amino acid limitation is a positive limitation—the peptide may not have fewer than 7 nor more than 30 amino acids. Applicants' position is unambiguous: the present peptides have between 7 and 30 peptides, including either 7 or 30, end of discussion subject to whatever ought to apply of the Doctrine of Equivalents. In other words, the recitation "7-30 amino acids" is not a tricky way of claiming significantly larger peptides or proteins which incidentally subsume substructures of 7-30 amino acids, and this very clarification should guide the construction of this claim language both now and when the need arises later.

The Office Action asserts that the first five amino acids 171-175 of MT hsp65 (GVITV) are identical to the corresponding amino acids of human hsp65, which is correct, but the Office Action then does not (and this is critical) go on to acknowledge that the claimed five amino acids are in a T cell epitope corresponding to a T cell epitope of a mammalian homologue. As correctly attributed to the cited reference, the sequence 171-240 comprises an epitope, but the epitope—the location of which is not stipulated in the reference—does not overlap with the amino acids 171-175 because Table I of the reference identifies that the referred to epitopes are present only within sequences 180-188 and 216-240 of the overall 171-240 sequence. The claimed subject matter is therefore not only not disclosed or taught by the reference, if one skilled in the art reads the reference (which is attributable to one of the co-inventors in any case, and whom understood the distinction from the outset) one would be directed very much away from the present invention. The asserted 102(b) rejection may thus be seen as in condition to be withdrawn.

Claims 24-25 and 29-32 stand rejected under 35 U.S.C. 112, first paragraph, for purported failure to meet the written description requirement. Applicants do describe their claimed subject matter generically, however, and even by the Examiner's assessment have provided at least two examples of species of that genus. There is no reason for skepticism that

additional species can be recognized and/or developed by those skilled in the art without undue experimentation—in fact, the very continued persistence of this prosecution despite the number of years’ prosecution already elapsed speaks volumes regarding the ease and value of practicing the present claims. For the same reason, the 35 U.S.C. 112, first paragraph rejection of claims 24-32 is respectfully traversed, because as the Examiner admits (and for which applicants are appreciative) the applicants have enabled nasal or oral administration of hsp65 to treat Th1 mediated diseases, and applicants urge that the ability of that enablement to represent the scope of the claims as presented is straightforward. After all, the claims are directed to mammalian stress proteins having a microbial counterpart, so the claims do not extend to “any microbial peptide from bacteria” at all, and this should put any concerns of the Examiner to rest. The specification gives a fair description of many stress proteins (page 4) which is in line with the breadth of the claims. The written description requirement is ripe for withdrawal because applicants have met their written description requirement.

As to routes of administration besides oral and nasal, one skilled in the art knows how to optimize alternative administration routes such as parenteral. The Examiner’s conclusion that “Wendling clearly teaches that parenteral administration did not suppress disease” is not a fair representation of the teaching of Wendling. As explained earlier in the prosecution of this patent application, a single lack of success is often overcome by routine adaptation of adjuvants and etc. and is not a general evidence of lack of enablement when applicants have put forth a more comprehensive presentation for which no fundamental basis for skepticism exists.

As to other inflammatory conditions besides Th1 mediated diseases, there does not appear to be support for the Examiner’s contention that the “mode of action of administering an hsp65 protein causes IL-10 production and subsequent down-regulation of T cell mediated events.” The cited later references only suggest that the mode of action may be through IL10 but does not exclude the possibility of other mechanisms—and the claimed invention is not about theoretical mechanisms anyway. The claimed invention is instead a method of treating one of certain diseases, an inflammatory disease, by administering a specific peptide in a way which is amply explained in the specification. The Examiner has not brought forth any basis for any skepticism that the disclosed and claimed invention is either overbroad or does not work as asserted, and absent such a basis the applicants are entitled to allowance of their claims.

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The outstanding Office Action is revealing in a very positive way, in that it identifies how few issues remain for resolution prior to allowance of the claims. Certain previous issues which do not appear in the Office Action, for which several years' prosecution were devoted, have now been long resolved. The above reassurances and especially the admission regarding claim construction are all that are necessary now for allowance of the pending claims. Claims 31 and 32, although not to the exclusion of the others, may particularly be seen as in condition for allowance.



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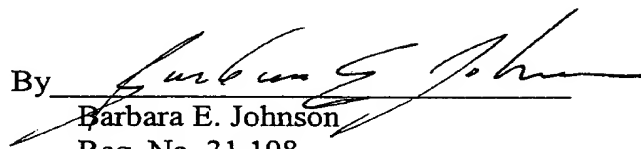
**CONCLUSION**

For all the foregoing reasons, pending claims 24-32 are ready for immediate allowance. Reconsideration of the rejections and allowance of pending claims 24-32 are respectfully requested.

Respectfully submitted,

THE WEBB LAW FIRM

By



Barbara E. Johnson  
Reg. No. 31,198  
Attorney for Applicants  
700 Koppers Building  
436 Seventh Avenue  
Pittsburgh, PA 15219-1845  
Telephone: 412-471-8815  
Facsimile: 412-471-4094  
E-mail: [webblaw@webblaw.com](mailto:webblaw@webblaw.com)

The dating stamp of the Patent Office on this card will be taken as an indication that the accompanying paper was filed.

Applicants: Stephen M. Anderton et al.

Appl. No. 08/716,169

Paper dated 07/08/2005

Att'y's File No. 470-961125

Amount of Check \$450.00

BEJ/dlr

{W0199677.1}

Patent Application entitled:

"Peptide Fragments of Microbial Stress Proteins and Pharmaceutical Composition Made Thereof for the Treatment and Prevention of Inflammatory Diseases"

Amendment Transmittal Letter (1 pg., in trip.); Amendment (7 pp.); Petition for Extension of Time (1 pg., in dup.); and check for \$450.00 (extension of time fee).

**RECEIVED**

JUL 12 2005

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